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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,242	10/01/2002	Goran Aslin	P4811US00/EB/MR	8790
466	7590	01/22/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			KOKABI, AZADEH	
			ART UNIT	PAPER NUMBER
			3743	
			DATE MAILED: 01/22/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,242

Applicant(s)

ASLIN ET AL.

Examiner

Azy Kokabi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 9, 32, 38, 39 and 41-45 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10-31, 33, 35-37 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 9, 32, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodson et al (U.S. Patent No. 5,347,998).

Hodson et al disclose a metered-dose breath-actuated inhaler including all the features recited in the claims. The embodiment described with reference to FIGS. 6-9 includes an activator for activating a canister to dispense medication in the form of cocking spring or pressure spring means (#86) and vane (#88). Hodson further discloses a return controller or which comprises a spring or return spring means (#99) that controls or biases the rocker element (#90) to a position that prevents activation of the canister when inhalation terminates. Hodson teaches that when a patient inhales through a mouthpiece (#76), the airflow causes pivotal movement of the vane (#88), which causes a curved surface (#96) to rotate and rotate a catch (#92) in an opposite direction. The catch moves from a blocking position to a non-blocking position and permits movement of the rocker element (#90), which in turn moves a canister (#74) relative to a valve stem (#78), thereby firing the valve and releasing a dose of medication. Further, Hodson discloses that the rocker element (#90) is biased by a spring (#99) to its blocking position when patient inspiration is halted” (see at least column 6, lines 25-28).

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In reference to claim 9, Hodson discloses monitoring means capable of detecting the time between activation and deactivation of the canister (see at least column 3, lines 60-68). In reference to claim 32, Hodson et al discloses a safety means that prevents activation of the inhaler when the safety means is in a non-operative state. The safety means takes the form of a timing mechanism associated with the priming mechanism for the inhaler (see at least column 7, lines 34-48). Figure 7 shows a housing holding the inhaler (#102).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 38, 39, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodson et al in view of Wakeman (U.S. Patent No. 3,151,618).

As previously set forth in paragraph 2 above, Hodson et al disclose all the limitations as set forth, however Hodson fails to disclose means for moving the mouthpiece from a rest

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position where the mouthpiece is arranged substantially within a body to an activated position where at least the front end of the mouthpiece protrudes from the body of the inhaler.

Wakeman discloses a canister-type inhaler that includes a mouthpiece (#30) that pivots from a position within the body of the inhaler (figure 1) to a position where the mouthpiece protrudes from the inhaler (see figures 1-4). The mouthpiece is held in the two positions by fixating means comprising a cap (#12) and a surface (#52) of the actuator against which the nozzle rests in the protruding position.

As seen in figures 1-4, the mouthpiece pivots about a pivot axis along a pin (#34) that is journaled in opening (#36). The actuator (#18) acts as a guide means limiting sliding movement of the mouthpiece along a longitudinal direction. The cap (#12) handles/covers the actuator that set the inhaler ready for delivery of a dose of medication.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the inhaler taught by Hodson et al to include a pivoting mouthpiece and cap arrangement as taught by Wakeman in order to make the inhaler more compact and less conspicuous when not in use (see Wakeman, at least column 1, lines 35-39).

Allowable Subject Matter

6. Claims 7-8, 10-31, 33, 35-37, 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive. Applicant argues that Hodson fails to disclose a return controller that deactivates the

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canister to close the opening when the airflow drops below a certain threshold value (see Applicant's remarks, pg. 22). Applicant argues that the return means of Hodson are all activated by an electrical response from either a time circuit or switches.

However, Hodson specifically teaches that a return controller (#99) controls the rocker element and it biases it back to a blocking position when patient inspiration is halted (see column 6, lines 25-28). Therefore, as patient inspiration is halted, the airflow in the canister drops below a certain value and the rocker element blocks the canister opening. This deactivates the canister. Electrical signs are used to reset the valve for reenergizing after firing of the medication. Furthermore, electromechanical means such as a motor and battery are used in Hodson reference is used to prime the canister for firing.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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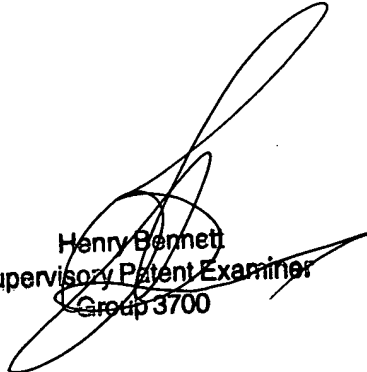
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

AK

11/20/04


Henry Bennett
Supervisory Patent Examiner
Group 3700